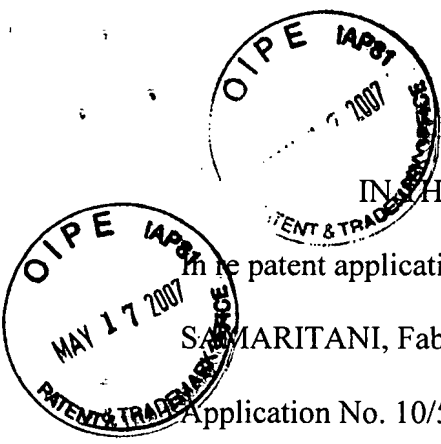


05-18-07

TFW



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of:

SAMARITANI, Fabrizio et al.

Application No. 10/561,529

Filed December 20, 2005

FREEZE-DRIED FSH/LH FORMULATIONS

)
) Before the Examiner
) Lorraine Spector
)
) Group Art Unit
) 1647
)
) Confirmation No.
) 9788

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

1. List of All Patents, Publications, U.S. Applications, or Other Information

Pursuant to the provisions of 37 CFR 1.56, 1.97, and 1.98, Applicant requests consideration of the references listed on the attached PTO/SB/08 form(s) (commonly referred to as a PTO-1449 form) and/or the additional information identified below.

☒ I hereby certify that this correspondence is being deposited with the United States Postal Service as "Express Mail Post Office to Addressee" addressed to Commissioner for Patents, Mail Stop Amendment, P.O. Box 1450, Alexandria, VA 22313-1450, Mailing Label No. EM 079404238 US, on the date indicated below.

Sandy Elston
Typed/printed name of person signing this certificate

[Signature]
Signature

May 17, 2007
Date

2. Enclosed Legible Copies

- 2a. A legible copy of each foreign patent document and publication listed on the PTO/SB/08 form is enclosed,
- ☐ i. except, a copy is not provided for each reference previously cited by or submitted to the Patent Office in prior U.S. Patent Application Serial No. _____, filed _____ from which the present application claims priority under 35 U.S.C. §120.
- ☐ ii. except, a copy is not provided for each cumulative reference and enclosed reference identified below:
- ☐ 2b. A copy of the specification and drawings for each cited unpublished U.S. application.
- ☐ 2c. A copy of a Search Report or Written Opinion from a foreign patent office is also enclosed.
- ☐ 2d. Consideration of the enclosed additional and/or below discussed information is requested.

3. Concise Explanation of Relevance for Non-English Language Information

For each non-English language reference listed on the attached SB/08 form(s), reference is made to:

- ☐ 3a. an English language translation submitted herewith,
- ☐ 3b. foreign patent office Search Report (in the English language) submitted herewith,
- ☐ 3c. an English language translation of a foreign patent office Search Report submitted herewith,
- ☐ 3d. the concise explanation contained in the present application at page(s) ___,
- ☐ 3e. the concise explanation set forth in the attached English language abstract,
- ☒ 3f. a copy of a related patent publication (in the English language) cited herewith,

Foreign Patent Document	Corresponding English Language Patent Document
DE 41 17 078 A1	WO 92/21332

☐ 3g. the following concise explanation: ____.

4. Time for Filing

☒ 4a. This Information Disclosure Statement is submitted:

- ☐ i. for U.S. national applications or national stage PCT applications (not including CPAs and RCEs), within 3 months of filing or entry into national stage; or
- ☒ ii. for U.S. national applications, national stage PCT applications, CPAs or RCEs, before the first Office Action on the merits,

and thus no certification and/or fee is required.

☐ 4b. This information Disclosure Statement is submitted after three months from the filing date and after the first Office Action on the merits, but prior to the mailing date of a final Office Action or Notice of Allowance, and thus:

- ☐ i. the statement specified in 37 CFR §1.97(e) is provided below, or
- ☐ ii. a fee of \$____ (set forth in 37 CFR §1.17(p)) is enclosed.

☐ 4c. This Information Disclosure Statement is submitted after the mailing date of a final Office Action or Notice of Allowance and prior to payment of the issue fee, and thus:

- ☐ i. the statement specified in 37 CFR §1.97(e) is provided below, and a fee of \$ (set forth in 37 CFR §1.17(p)) is enclosed, or
- ☐ ii. a Request for Continued Examination (RCE) and fee of 37 CFR §1.17(e) has been filed.

☐ 4d. This Information Disclosure Statement is submitted after payment of the issue fee, and thus:

- i. a Petition to Withdraw from Issue pursuant to 37 CFR §1.313(c)(2) has been filed, and
- ii. a Request for Continued Examination (RCE) and fee of 37 CFR §1.17(e) has been filed.

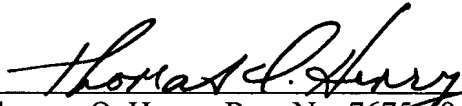
5. Certification- Statement Under 37 CFR 1.97(e)

- ☐ 5a. It is hereby certified that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.
- ☐ 5b. A copy of a dated communication from a foreign patent office which clearly shows the statement is being submitted within three (3) months of the date on the communication is enclosed.
- ☐ 5c. It is hereby certified that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to my knowledge after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

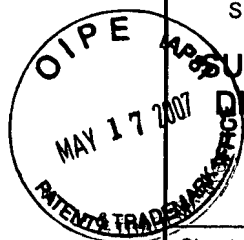
The filing of this Information Disclosure Statement shall not be construed as an admission that the information cited is, or is considered to be, material to patentability as defined in §1.56(b). It is believed that no additional fees are required. Should any other fee be required, however, please charge such fee to Deposit Account No. 23-3030, but not to include any payment of issue fees.

Respectfully submitted,

By


Thomas Q. Henry, Reg. No. 7675-49
Woodard, Emhardt, Moriarty, McNett & Henry LLP
111 Monument Circle, Suite 3700
Indianapolis, Indiana 46204-5137
(317) 634-3456

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number



Substitute for form 1449/PTO

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known

Application Number	10/561,529
Filing Date	December 20, 2005
First Named Inventor	SAMARITANI, Fabrizio et al.
Art Unit	1647
Examiner Name	Lorraine Spector
Attorney Docket No.	7541-5

Sheet 1 of 2

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (If known)				
		US	4,496,537	01-29-1985	Kwan, Henry K.	
		US	4,589,402	05-20-1986	Hodgen, et al.	
		US	4,659,696	04-21-1987	Hirai, et al.	
		US	4,670,419	06-02-1987	Uda, et al.	
		US	4,746,508	05-24-1998	Carey, et al.	
		US	4,496,537	01-29-1985	Kwan, Henry K.	
		US	4,962,091	10-09-1990	Eppstein, et al.	
		US	5,087,615	02-11-1992	Chappel, et al.	
		US	5,128,453	07-07-1992	Arpaia, et al.	
		US	5,162,306	11-10-1992	Donaldson	
		US	5,270,057	12-14-1993	de Meere, et al.	
		US	5,356,876	10-18-1994	Espey, Lawrence L	
		US	5,374,620	12-20-1994	Clark, et al.	
		US	5,384,132	01-24-1995	De Meere, et al.	
		US	5,508,261	04-16-1996	Moyle, et al.	
		US	5,580,856	12-03-1996	Prestrelski, et al.	
		US	5,639,640	06-17-1997	Reddy, et al.	
		US	5,650,390	07-22-1997	Samaritani, et al.	
		US	5,661,125	08-26-1997	Strickland, Thomas Wayne	
		US	5,681,822	10-28-1997	Bornstein, et al.	
		US	5,733,572	03-31-1998	Unger, et al.	
		US	5,767,067	06-16-1998	Arpaia, et al.	
		US	5,811,096	09-22-1988	Aleman, et al.	
		US	5,889,110	03-30-1999	Hutchinson, et al.	
		US	5,929,028	07-27-1999	Skrabanja, et al.	
		US	5,945,187	08-31-1999	Buch-Rasmussen, et al.	
		US	6,066,620	05-23-2000	McGregor, et al.	
		US	6,136,784	10-24-2000	L'Italien, et al.	
		US	6,238,890	05-29-2001	Boime, et al.	
		US	6,267,958	07-31-2004	Andya, et al.	
		US	6,440,930	08-27-2002	Rinella, Jr., Vincent Joseph	

Examiner Signature	Date Considered
-----------------------	--------------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449/PTO

**SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT BY
APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application Number	10/551,840
Filing Date	December 20, 2005
First Named Inventor	SAMARITANI, Fabrizio et al.
Art Unit	1647
Examiner Name	Lorraine Spector
Attorney Docket No.	7541-5

Sheet	2	of	2
-------	---	----	---

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)	MM-DD-YYYY		
		US 6,541,606	04-01-2003	Margolin, et al.	
		US 6,573,237	06-03-2003	Rinella, Jr., Vincent Joseph	
		US 2003/0072803	04-27-2003	Goldenberg, et al.	

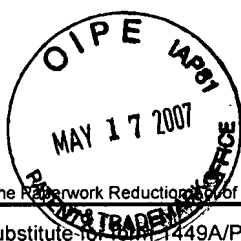
FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)	MM-DD-YYYY			
		DE 41 17 078 A1	11-25-1882	Lohmann et al.		<input type="checkbox"/>
		EP 0 318 081	05-31-1989	Jansen, et al.		<input type="checkbox"/>
		EP 0 448 146	09-25-1991	De Ruiter, Marinus Arie		<input type="checkbox"/>
		EP 0 603 159	06-22-1994	Pearlman, et al.		<input type="checkbox"/>
		EP 0 652 766	07-29-1993	O'Connor, et al.		<input type="checkbox"/>
		EP 0 668 073	04-14-1999	Igari, et al.		<input type="checkbox"/>
		EP 0 736 303	08-25-1999	Gross, et al.		<input type="checkbox"/>
		EP 0 853 945	07-22-1998	Skrabanja, et al.		<input type="checkbox"/>
		EP 0 891 774	01-20-1999	Takada, et al.		<input type="checkbox"/>
		EP 0 920 873	12-07-1998	Chang, et al.		<input type="checkbox"/>
		EP 0 974 359	01-26-2000	Hoffmann, et al.		<input type="checkbox"/>
		EP 1 191 099	06-30-1999	Itoh, et al.		<input type="checkbox"/>
		CA 1,340,132	11-17-1998	Donaldson, Lloyd E.		<input type="checkbox"/>
		FR 2782455	02-25-2000	Aleman, et al.		<input type="checkbox"/>
		GB 1065127	04-12-1967	Serono 1 st Farm		<input type="checkbox"/>
		GB 839,300	08-25-1958	Organon Laboratories Limited		<input type="checkbox"/>
		WO 92/21332	12-10-1992	Lohmann, et al.		<input type="checkbox"/>
		WO 92/22568	12-23-1992	Moyle, et al.		<input type="checkbox"/>
		WO 93/11788	06-24-1993	Samaritani, et al.		<input type="checkbox"/>
		WO 94/03198	02-17-1994	O'Connor, et al.		<input type="checkbox"/>
		WO 97/04801	02-13-1997	Andya, et al.		<input type="checkbox"/>
		WO 97/17087	05-15-1997	De Young, et al.		<input type="checkbox"/>
		WO 98/30592	07-16-1998	Hein, et al.		<input type="checkbox"/>
		WO 99/21534	05-06-1999	Tallavajhala, et al.		<input type="checkbox"/>

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

#463778

WEEMH #112894 (Rev. 1/06)



WEMMH PTO/SB/08b (09-06)

Approved for use through 03/31/2007. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for Form 1449A/PTO				Complete if Known	
SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Application Number	10/561,529
				Filing Date	December 20, 2005
				First Named Inventor	SAMARITANI, Fabrizio et al.
				Art Unit	1647
				Examiner Name	Lorraine Spector
Sheet	1	of	7	Attorney Docket No.	7541-5

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s) publisher, city and/or country where published	T ⁶
		AKERS Michael J., "Considerations in selecting antimicrobial preservative agents for parenteral product development", Pharmaceutical Technology, May 1984, pp. 36-46.	<input type="checkbox"/>
		AKERS, Michael J., "Excipient – Drug Interactions in Parenteral Formulations", Journal of Pharmaceutical Sciences, November 2002, Vol. 91, No. 11, pp. 2283-2300	<input type="checkbox"/>
		AMIR, Syed M. et al., "Phenol, A Potent Stimulator of Adenylate Cyclase in Human Thyroid Membranes", Endocrine Research Communications, 8(2):83-95, 1981.	<input type="checkbox"/>
		A.P.L.® Injection 5 000 IU and Injection 10 000 IU, http://home.intekom.com/pharm/akromed/apl-inj.html , December 12, 2002, pp. 1-2.	<input type="checkbox"/>
		A.P.L.® (chorionic gonadotropin for injection, USP), For Intramuscular Injection Only, Physicians' Desk Reference, 51 st Edition, p. 2805.	<input type="checkbox"/>
		A.P.L.®, Physicians' Desk Reference, 12 th Edition, page 625.	<input type="checkbox"/>
		A.P.L.®, Physicians' Desk Reference, 19 th Edition, page 537.	<input type="checkbox"/>
		A.P.L.®, Physicians' Desk Reference, 34 th Edition, page 592.	<input type="checkbox"/>
		ARZNEIFORMENLEHRE, Paul Heinz List, Wissenschaftliche Verlagsgesellschaft mbH, Stuttgart, 4th Edition, 1985, pp. 402-407.	<input type="checkbox"/>
		Asellacrin®, Physicians' Desk Reference, 34 th Edition, pp. 1605-1606.	<input type="checkbox"/>
		Asellacrin®, Physicians' Desk Reference, 39 th Edition, pp. 1940-1941.	<input type="checkbox"/>
		BOIME, Irving et al., "Glycoprotein Hormone Structure-Function and Analog Design", Recent Progress in Hormone Research, Vol. 54, 1999, The Endocrine Society, pp. 271-289.	<input type="checkbox"/>
		BONTEMPO, John A., "Chapter 5: Formulation Development", Development of Biopharmaceutical Parenteral Dosage Forms, pp. 109-142, published by Marcel Dekker, Inc.	<input type="checkbox"/>
		COMBARNOUS, Yves, "Molecular Basis of the Specificity of Binding of Glycoprotein Hormones to Their Receptors", Endocrine Reviews, 1992. Vol. 13, No. 4, pp. 670-691.	<input type="checkbox"/>
		CPMP Guidelines antimicrobial preservative inclusion, CPMP/CVMP/OWP/115/95, July 8, 1997, pp. 1-6.	<input type="checkbox"/>
		de MEDEIROS, S.F. et al., "Stability of Immunoreactive β -Core Fragment of hCG", Obstetrics & Gynecology, Vol. 77, No. 1, January 1991, pp. 53-59.	<input type="checkbox"/>
		Epogen®, Physicians' Desk Reference, 51 st Edition, pp. 489-494.	<input type="checkbox"/>

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional).

²Applicant is to place a check mark here if English language Translation is attached#449528

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/561,529
				Filing Date	December 20, 2005
				First Named Inventor	SAMARITANI, Fabrizio et al.
				Art Unit	1647
				Examiner Name	Lorraine Spector
Sheet	2	of	7	Attorney Docket No.	7541-5

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s) publisher, city and/or country where published	T ²
		Fertinex™ (urofollitropin for injection, purified) for subcutaneous injection, Physicians' Desk Reference, 53 rd Edition, pp. 2988-2989, published by Medical Economics Company, Inc.	<input type="checkbox"/>
		Fertinex®, Physicians' Desk Reference, 55 th Edition, pp. 3020-3022.	<input type="checkbox"/>
		Follistim™ (follitropin beta for injection), Physicians' Desk Reference, 53 rd Edition, pp. 2128-2132, published by Medical Economics Company, Inc.	<input type="checkbox"/>
		Follistim®, Physicians' Desk Reference, 54 th Edition, pp. 2092-2095.	<input type="checkbox"/>
		Follutein®, Physicians' Desk Reference, 24 th Edition, pp. 1249-1250.	<input type="checkbox"/>
		FRANSSON, Jonas et al., "Solvent Effects on the Solubility and Physical Stability of Human Insulin-Like Growth Factor 1", Pharmaceutical Research 14(5):606-12, 1997.	<input type="checkbox"/>
		FRENKEN, L.A.M. et al., "Analysis of the Efficacy of Measures to Reduce Pain After Subcutaneous Administration of Epoetin Alfa", Nephrology Dialysis Transplantation 9:1295-98, 1994.	<input type="checkbox"/>
		FURUHASHI, M. et al. "Fusing the Carboxy-Terminal Peptide of the Chorionic Gonadotropin (CG) beta Subunit to the Common alpha-Subunit: Retention of O-linked Glycosylation and Enhanced in Vivo Bioactivity of Chimeric Human CG", Molecular Endocrinology, 1995, Vol. 9, No. 1, pages 54-63.	<input type="checkbox"/>
		GARCIA-CAMPAYO, Vincenta et al., "Design of Stable Biologically Active Recombinant Lutropin Analogs", Nature Biotechnology 15:663-67, 1997.	<input type="checkbox"/>
		GENNARO et al., "Parenteral Preparations", Chapter 84, Remington's Pharmaceutical Sciences (18th Edition, Mack Publishing. Co., 1990, see part 8 "Pharmaceutical Preparations and their Manufacture," pp. 1545-1569.	<input type="checkbox"/>
		Glucagon, Physicians' Desk Reference, 19 th Edition, pp. 703-704.	<input type="checkbox"/>
		Glukor®, Physicians' Desk Reference, 19 th Edition, page 844.	<input type="checkbox"/>
		Gonal-F®, (follitropin alfa for injection), for subcutaneous injection, Physicians' Desk Reference, 53 rd Edition, pp. 2991-2995, published by Medical Economics Company, Inc.	<input type="checkbox"/>
		Gonal-F® (follitropin alfa for injection) For subcutaneous injection: Package Insert Code N1900101B, manufactured by Serono Laboratories, Inc., Randolph, MA, USA, published September, 1997.	<input type="checkbox"/>
		Gonal-F®, Physicians' Desk Reference, 54 th Edition, pp. 2942-2946.	<input type="checkbox"/>
		HANSON, Musetta A. et al., "Introduction to Formulation of Protein Pharmaceuticals", Chapter. 7, pp. 209 – 233.	<input type="checkbox"/>

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional).

²Applicant is to place a check mark here if English language Translation is attached.

#463330

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/561,529
				Filing Date	December 20, 2005
				First Named Inventor	SAMARITANI, Fabrizio et al.
				Art Unit	1647
Examiner Name	Lorraine Spector				
Sheet	3	of	7	Attorney Docket No.	7541-5

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s) publisher, city and/or country where published	T ²
		HARVEY, Stewart C., "Antiseptics and Disinfectants; Fungicides; Ectoparasitocides", The Pharmacological Basis of Therapeutics, 6 th Edition, Chapter 41, 964-987, 1980.	<input type="checkbox"/>
		HEIKOOP, Judith C. et al., "Structure-based design and protein engineering of intersubunit disulfide bonds in gonadotropins" Nature Biotechnology, July 1997, Volume 15, pp. 658-62.	<input type="checkbox"/>
		Package insert HRF, "HRF* Injection 0,1 mg and HRF* Injection 0,5 mg", Malahyde Information Systems, 2003, pp.1-4.	<input type="checkbox"/>
		Humatrope®, Physicians' Desk Reference, 44 th Edition, pp. 1216-1217.	<input type="checkbox"/>
		Humegon®, Physicians' Desk Reference, 54 th Edition, pp. 2095-2097.	<input type="checkbox"/>
		JORGENSEN, Jan Trost, "Improvement of Patient Convenience in Treatment with Growth Hormone", Journal of Pediatric Endocrinology, 1994, 7(2):175-180.	<input type="checkbox"/>
		KEENE et al., Expression of Biologically Active Human Follitropin in Chinese Hamster Ovary Cells. The Journal of Biological Chemistry Vol. 264/9: 4769-4775.	<input type="checkbox"/>
		KESNER, J.S. et al., "Stability of Urinary Female Reproductive Hormones Stored Under Various Conditions", Reproductive Toxicology, Vol. 9, No. 3, pp. 239-244, 1995.	<input type="checkbox"/>
		LAM, Xanthe M. et al., "The Effect of Benzyl Alcohol on Recombinant Human Interferon-γ" Pharmaceutical Research, 1997, Vol. 14, No. 6, 725-729.	<input type="checkbox"/>
		LEUKINE Package Insert/Approved Text, Rev. 0230-02, Issued February, 1998, pp 1-30.	<input type="checkbox"/>
		LIVESEY J. H. et al., "Glycerol prevents loss of immunoreactive follicle-stimulating hormone and luteinizing hormone from frozen urine", Journal of Endocrinology, Vol. 98, pp. 381-384, 1983.	<input type="checkbox"/>
		LIVESEY, J. H. et al., "Effect of Time, Temperature and Freezing on the Stability of Immunoreactive LH, FSH, TSH, Growth Hormone, Prolactin and Insulin in Plasma", The Medical Unit, Princess Margaret Hospital, Christchurch 2, New Zealand, June 25, 1980, Biochem 13 (4), 1980, pp. 151-155.	<input type="checkbox"/>
		MAA, Yuh-Fun, et al., "Aggregation of recombinant human growth hormone induced by phenolic compounds", International Journal of Pharmaceutics, 1996, Vol. 140, pp. 155 - 168.	<input type="checkbox"/>
		Metrodin®, Physicians' Desk Reference, 51 st Edition, pp. 2616-2618.	<input type="checkbox"/>
		Pergonal®, Physician's Desk Reference, 29 th Edition, pp. 1366-1367.	<input type="checkbox"/>

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional).

²Applicant is to place a check mark here if English language Translation is attached.

#463330

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/561,529
				Filing Date	December 20, 2005
				First Named Inventor	SAMARITANI, Fabrizio et al.
				Art Unit	1647
				Examiner Name	Lorraine Spector
Sheet	4	of	7	Attorney Docket No.	7541-5

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s) publisher, city and/or country where published	T ²
		Pergonal®, Physician's Desk Reference, 49 th Edition, pp. 2335-2337.	<input type="checkbox"/>
		Pergonal®, Physician's Desk Reference, 51 st Edition, pp. 2618-2620.	<input type="checkbox"/>
		Pergonal®, Physician's Desk Reference, 54 th Edition, pp. 2946-2947.	<input type="checkbox"/>
		PIMPALKHUTE, M. et al., "Radioimmunoassay of Human Follicle Stimulating Hormone/HFSH", J. Radioanal. Nucl. Chem. Letters, 1986, 103, No. 2, pp. 105-116.	<input type="checkbox"/>
		Pregnyl®, Physicians' Desk Reference, 39 th Edition, page 1450.	<input type="checkbox"/>
		Pregnyl® (chorionic gonadotropin for injection, USP), Physicians' Desk Reference, 51 st Edition, p. 1878.	<input type="checkbox"/>
		Pregnyl Prescribing Information, "Pregnyl (chorionic gonadotropin for injection, USP), Organon Inc., August 1998, pp. 1-4.	<input type="checkbox"/>
		Procrit®, Physicians' Desk Reference, 51 st Edition, page 1896.	<input type="checkbox"/>
		Profasi® (chorionic gonadotropin for injection, USP) for Intramuscular Injection, Physicians' Desk Reference, 51 st Edition, pp. 2620-21.	<input type="checkbox"/>
		Profasi (chorionic gonadotropin for injection, USP) for intramuscular injection, Serono Laboratories, Inc. (revised June 1993).	<input type="checkbox"/>
		Progon®, Physicians' Desk Reference, 19 th Edition, page 646.	<input type="checkbox"/>
		Protropin®, Physicians' Desk Reference, 44 th Edition, pp. 1002-1003.	<input type="checkbox"/>
		RAFFERTY, M.J. et al., "Safety and Tolerability of a Multidose Formulation of Epoetin Beta in Dialysis Patients", Clinical Nephrology. 54(3):240-45, 2000.	<input type="checkbox"/>
		Regular Iletin®, Physicians' Desk Reference 19 th Edition, page 705.	<input type="checkbox"/>
		REMMELE Jr., Richard L. et al., "Interleukin-1 Receptor (IL-1R) Liquid Formulation Development Using Differential Scanning Calorimetry", Pharmaceutical Research, 1998, Vol. 15, No. 2 pp. 200-208.	<input type="checkbox"/>
		ROSE, M.P. et al, "Characterisation, calibration and comparison by international collaborative study of international standards for the calibration of therapeutic preparations of FSH", Journal of Endocrinology, Vol. 158, pp. 97-114, 1998.	<input type="checkbox"/>

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional).

²Applicant is to place a check mark here if English language Translation is attached.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/561,529
				Filing Date	December 20, 2005
				First Named Inventor	SAMARITANI, Fabrizio et al.
				Art Unit	1647
Examiner Name	Lorraine Spector				
Sheet	5	Of	7	Attorney Docket No.	7541-5

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s) publisher, city and/or country where published	T ²
		RYAN, Robert J. et al., "Some physical and Hydrodynamic Properties of Human FSH and LH", Mayo Clinic and Mayo Foundation: Section of Endocrine Research, Rochester, Minnesota; and Department of Biochemistry, University of Illinois, Chicago, Illinois, pp. 105-137.	<input type="checkbox"/>
		ST. PETER, Wendy L. et al., "Pain Comparison After Subcutaneous Administration of Single-Dose Formulation Versus Multidose Formulation of Epogen in Hemodialysis Patients", American Journal of Kidney Diseases, 32(3):470-74, 1998.	<input type="checkbox"/>
		Saizen®, Physicians' Desk Reference, 52 nd Edition, pp. 2776-2777.	<input type="checkbox"/>
		SAKETOS, Maria et al., "Time-Resolved Immunofluorometric Assay and Specimen Storage Conditions for Measuring Urinary Gonadotropins", Clinical Chemistry, Vol. 40, No. 5, 1974, pp. 749-753.	<input type="checkbox"/>
		SAXENA, B.B. et al., "Amino Acid Sequence of the β Subunit of Follicle-stimulating Hormone from Human Pituitary Glands", The Journal of Biological Chemistry, Vol. 251, No. 4, pp. 993-1005, February 25, 1976.	<input type="checkbox"/>
		SERONO Study Report GF 9873, "Evaluation of FSH Formulations claimed in EP-974'359", dated March 22, 2004.	<input type="checkbox"/>
		SHOEMAKER, J. et al., "New Approaches with the FSH Threshold Principle in Polycystic Ovarian Syndrome", Annals New York Academy of Sciences, pp. 296-300.	<input type="checkbox"/>
		SHOME, B. et al., "Human Follicle Stimulating Hormone: First Proposal for the Amino Acid Sequence of the Hormone-Specific, β Subunit (hFSH β)", J. Clin. Endocrinol. Metab., Vol. 39, 187, pp. 203-205, 1974.	<input type="checkbox"/>
		Stemutrolin®, Physicians' Desk Reference, 24 th Edition, page 867.	<input type="checkbox"/>
		STRICKLAND, Thomas W. et al, "The Kinetic and Equilibrium Parameters of Subunit Association and Gonadotropin Dissociation", The Journal of Biological Chemistry, 1982, Vol. 257, No. 6 pp. 2954-2960.	<input type="checkbox"/>
		Package insert Suprefact.	<input type="checkbox"/>
		SUGAHARA, Tadashi et al., "Expression of biologically active fusion genes encoding the common α subunit and either the CG β or FSH β subunits: role of a linker sequence", Molecular and Cellular Endocrinology 125 (1996) pp. 71-77.	<input type="checkbox"/>
		"The United States Pharmacopeia, Twenty-First Revision", United States Pharmacopeial Convention, Inc., Official from January 1, 1985, prepared by the Committee of Revision and published by the Board of Trustees, pp. 1491-1493, 1984.	<input type="checkbox"/>
		VAHL, et al., "Bioavailability of Recombinant Human Growth Hormone in Different Concentrations and Formulations", Pharmacology & Toxicology 79:144-49, 1996.	<input type="checkbox"/>
		VOORTMAN, Gerrit et al, "Bioequivalence of subcutaneous injections of recombinant human follicle stimulating hormone (Puregon®) by Pen-injector and syringe", Human Reproduction, 1999, Vol. 14, No. 7, pp. 1698-1702.	<input type="checkbox"/>

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional).

²Applicant is to place a check mark here if English language Translation is attached.

#463330

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/561,529
				Filing Date	December 20, 2005
				First Named Inventor	SAMARITANI, Fabrizio et al.
				Art Unit	1647
Examiner Name	Lorraine Spector				
Sheet	6	of	7	Attorney Docket No.	7541-5

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s) publisher, city and/or country where published	T ²
		WALLHAUSSER K-H, "Antimicrobial Preservatives in Europe: Experience with Preservatives Used in Pharmaceuticals and Cosmetics", International Symposium on Preservation in Biological Products, San Francisco 1973, Develop. Biol. Standard, Vol. 24, pp. 9-28, 1974.	<input type="checkbox"/>
		ANCHORDOQUY, Thomas J. et al., "Polymers Protect Lactate Dehydrogenase during Freeze-Drying by Inhibiting Dissociation in the Frozen State", Archives of Biochemistry and Biophysics, Vol. 332, No. 2, August 15, 1996, Article No. 0337, pp. 231-238.	<input type="checkbox"/>
		ANIK, Shabbir T. et al., "Adsorption of D-Nal(2) ⁶ LHRH, a decapeptide, onto glass and other surfaces", Institute of Pharmaceutical Sciences, Syntax Research, Palo Alto, CA, International Journal of Pharmaceutics, Vol. 16, 1983, pp. 181-190.	<input type="checkbox"/>
		BAM, Narendra B. et al. "Stability of Protein Formulations: Investigation of Surfactant Effects by a Novel EPR Spectroscopic Technique", Research Article, Pharmaceutical Research, Vol. 12, No. 1, 1995, pp. 2-11.	<input type="checkbox"/>
		BASELGA, Jose et al., "Phase II Study of Weekly Intravenous Recombinant Humanized Anti-p185 ^{HER2} Monoclonal Antibody in Patients with HER2/ <i>neu</i> -Overexpressing Metastatic Breast Cancer", Journal of Clinical Oncology, Vol. 14, No. 3, March 1996, pp.737-744.	<input type="checkbox"/>
		BOULET, Louis-Philippe et al., "Inhibitory Effects of an Anti-IgE Antibody E25 on Allergen-induced Early Asthmatic Response", "Am J Respir Crit Care Med.", Vol. 155, 1997, pp. 1835-1840.	<input type="checkbox"/>
		BUTT, W. R., "The Iodination of Follicle-Stimulating and Other Hormones for Radiimmunoassay", J. Endocr., 1972, Vol. 55, pp. 453-454.	<input type="checkbox"/>
		JENTOFT, Neil, "Why are proteins O-glycosylated?", TIBS 15, August 1990, Elsevier Sciences Publishers Ltd. (UK), pp. 291-294.	<input type="checkbox"/>
		KETELSLEGERS, J.-M et al., "Receptor Binding Properties of ¹²⁵ I-hFSH Prepared by Enzymatic Iodination", Submitted August 30, 1974, J. Clin. Endocrinol Metab, Vol. 39, No. 6, 1974, pp. 1159-1162.	<input type="checkbox"/>
		KIBBE, Arthur H. (Editor), "Benzyl Alcohol", Handbook of Pharmaceutical Excipients, Third Edition, American Pharmaceutical Association, 2000, pp.41-43.	<input type="checkbox"/>
		MARANA, R. et al., "Influence of the Purity of the Iodinated Tracer on the Specificity of the Radioimmunoassay of Human Follicle-Stimulating Hormone", Acta Endocrinologica, Vol. 92, 1979, pp. 585-598.	<input type="checkbox"/>
		MIYACHI, Yuktaka, et al., "Structural Integrity of Gonadotropins after Enzymatic Iodination", Biochemical and Biophysical Research Communications, Vol. 46, No. 3, 1972, pp. 1213-1221.	<input type="checkbox"/>
		MIZUTANI, Takaharu et al., "Estimation of Adsorption of Drugs and Proteins on Glass Surfaces with Controlled Pore Glass as a Reference", Journal of Pharmaceutical Sciences, Vol. 67., No. 8, August 1978, American Pharmaceutical Association, pp. 1102-1105	<input type="checkbox"/>
		MIZUTANI, Takaharu, et al., "Study of Protein Adsorption on Glass Surfaces with a Hydrophobic Fluorescent Probe", Chem. Pharm. Bulletin, Volume 32, No. 6, 1984, pp. 2395-2400.	<input type="checkbox"/>

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional).

²Applicant is to place a check mark here if English language Translation is attached.

#463330

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/561,529
				Filing Date	December 20, 2005
				First Named Inventor	SAMARITANI, Fabrizio et al.
				Art Unit	1647
				Examiner Name	Lorraine Spector
Sheet	7	Of	7	Attorney Docket No.	7541-5

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s) publisher, city and/or country where published	²
		NEWMAN et al. "Use of Nonionic Block Copolymers in Vaccines and Therapeutics", Critical Reviews in Therapeutic Drug Carrier Systems, 1998, Vol. 15, No. 2, pp. 89-140.	<input type="checkbox"/>
		PIKAL, Michael J. et al., "The Effects of Formulation Variables on the Stability of Freeze-Dried Human Growth Hormone", Pharmaceutical Research, Vol. 8, No. 4, 1991, pp. 427-436.	<input type="checkbox"/>
		PINTO, Heidi et al., "Preparation of High-Quality Iodine-125-Labelled Pituitary Human Follicle-Stimulating Hormone (hFSH) For Radioimmunoassay: Comparison of Enzymatic and Chloramine-T Iodination", Clinica Chimica Acta, Elsevier/North-Holland Biomedical Press, Vol. 76, 1977, pp. 25-34.	<input type="checkbox"/>
		RATHNAM, P. et al., "Studies on Modification of Tryptophan, Methionine, Tyrosine and Arginine Residues of Human Follicle-Stimulating Hormone and Its Subunits", Biochimica et Biophysica Acta, Vol. 576, 1979, Elsevier/North-Holland Biomedical Press, pp. 81-87.	<input type="checkbox"/>
		SILBERRING, Jerzy et al., "A Universal and Simple Chloramine T Version for Hormone Iodination", International Journal of Applied Radiation and Isotopes, Vol. 33, 1982, pp. 117-119.	<input type="checkbox"/>
		STANKOV, B. M. et al., "The Effect of the Purity of the Iodinated Tracer on the Specificity of a Homologous Assay of Ovine Follicle Stimulating Hormone", Biochemistry International, Vol. 12, No. 1, January 1986, pp.11-19.	<input type="checkbox"/>
		SUGINAMI, H. et al., "Influence of the Purity of the Iodinated Tracer on the Specificity of the Radiomunoassay of Human Luteinizing Hormone", Acta Endocrinologica, Vol. 89, 1978, pp.506-520.	<input type="checkbox"/>
		SWINYARD, Ewart et al., "Pharmaceutical Necessities", Chapter 68, pp.1278-1280.	<input type="checkbox"/>
		TERADA, Shigeyuki, "Iodination of Luteinizing Hormone-Releasing Hormone", Biochemistry 1980, Vol. 19, pp. 2572-2576.	<input type="checkbox"/>
		"Urofollitropin", European Pharmacopia 2001, 1997:0958 (last revised version of 2001), pp. 1-6.	<input type="checkbox"/>
		VAN den STEEN, Philippe et al., "Concepts and Principles of O-Linked Glycosylation", hCG papers / CTP extensions / Boime papers, Critical Reviews in Biochemistry and Molecular Biology, Vol., 35, No. 3, 1998, pp. 151-208.	<input type="checkbox"/>
		WANG, Yu-Chang John et al., "Review of Excipients and pH's for Parenteral Products Used in the United States", Journal of the Parenteral Drug Association, Vol. 34, No. 6, November-December, 1980, pp. 452-462.	<input type="checkbox"/>
		WALSH, Gary, "Pharmaceutical biotechnology products approved within the European Union", European Journal of Pharmaceutics and Biopharmaceutics, Vol. 55, 2003, pp. 3-10.	<input type="checkbox"/>
		WATERMAN, Kenneth C. et al., "Stabilization of Pharmaceuticals to Oxidative Degradation", Pharmaceutical Development and Technology, Vol. 7, No. 1, 2002, pp. 1-32.	<input type="checkbox"/>
		WENZEL et al. "Pluronic F127 gel formulations of Deslorelin and GnRH reduce drug degradation and sustain drug release and effect in cattle", Journal of Controlled Release, 2002, Vol. 85, pp. 51-59.	<input type="checkbox"/>
		XING, Yongna et al., "Threading of a glycosylated protein loop through a protein hole: Implications for combination of human chorionic gonadotropin subunits", Protein Science, Vol. 10, 2001, pp. 226-235.	<input type="checkbox"/>

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional).

²Applicant is to place a check mark here if English language Translation is attached.

#463330